DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
January 17, 2001

WARNING LETTER

Mr. Saul Phillips
President/Owner
Export Inc.
19 West 7th Street
Barnegat Light, NJ 08006

FILE NO: 01-NWJ-16

Dear Mr. Phillips:

On September 7 and 18, 2000, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility located at the above address. The inspection was conducted to determine compliance with FDA's seafood processing regulations (Title 21 of the Code of Federal Regulations (CFR) Part 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection documented deficiencies which cause your scombrotoxin-forming seafood processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

Domestic issues:

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving Critical Control Point (i.e. core temperature of each fish) listed in your HACCP plan for scombrotoxin-forming species of fish (large tuna, mahi-mahi, and wahoo). Specifically, you did not record the internal temperature of each fish on 9/03/00 during the receipt of 13 tuna from the recreational vessel [redacted].

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombrotoxin-forming species of fish (large tuna, mahi-mahi, and wahoo) lists the critical limits, "Not to exceed 50 degrees F. internally" and "Ice level to cover fish in box", at the receiving critical control point. These critical limits are not adequate to control scombrotoxin (histamine) formation. The time of death of the fish will affect what internal temperature the fish should be at receiving (50 degrees F or below if the fish is delivered between 12 and 24 hours after the time of death, or 40 degrees F or below if the fish is delivered more than 24 hours after the time of death). Adequate receiving critical limits would also include parameters for harvest vessel records and sensory evaluation or histamine testing.

3. You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have HAACP plans for red snapper, bluefish, Spanish mackerel, and Boston mackerel to control the food safety hazard of histamine.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include seizure or injunction under the Act. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union (EU) certificates. As you know, FDA, as a service to the U.S. seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU food safety requirements. Unless the above deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipments.

We received a copy of your response dated November 10, 2000. In order to complete our review, we need a copy of your updated HACCP plan as well as a copy of your receiving records (internal temperatures, harvest vessel records, etc.) for the month of December. Please send your response within 15 working days of receipt of this letter. If you cannot send a response within 15 working days, state the reason for the delay and time frame within which the corrections will be completed.

Your written reply should be directed to the Food and Drug Administration, Attention: Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054, telephone (973) 526-6006.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District